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10/783,078	02/20/2004	Deborah L. Dihel	3049.SPD	6271

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NATIONAL STARCH AND CHEMICAL COMPANY  
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EXAMINER
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GEORGE, KONATA M

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/783,078  
Filing Date: February 20, 2004  
Appellant(s): DIHEL ET AL.

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David LeCroy  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed February 13, 2008 appealing from the Office action mailed November 20, 2007.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is deficient. 37 CFR 41.37(c)(1)(v) requires the summary of claimed subject matter to include: (1) a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, referring to the specification by page and line number, and to the drawing, if any, by reference characters and (2) for each independent claim involved in the appeal and for each dependent claim argued separately, every means plus function

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and step plus function as permitted by 35 U.S.C. 112, sixth paragraph, must be identified and the structure, material, or acts described in the specification as corresponding to each claimed function must be set forth with reference to the specification by page and line number, and to the drawing, if any, by reference characters. The brief is deficient because applicant claim that claim 1 is the only pending independent claim. This is incorrect claims 6 and 12 are both independent claims. Claim 6 is directed to "A dissolvable film having disposed on at least one surface thereof an encapsulated substance." And claim 12 is directed to "A method of preserving the flavor of an active to be delivered by a film, the method comprising encapsulating the active in a water soluble encapsulant and placing the encapsulated active on the surface of the film.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

7,025,983

Leund et al.

4-2006

### **(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leung et al. (US 7,025,983).

Applicant claims a method of making a dissolvable film comprising a substance, which is dispersed onto the surface of the film. Also, claimed are the film and a method of preserving the flavor of an active by the film as claimed.

***Determination of the scope and content of the prior art***  
**(MPEP §2141.01)**

Leung et al. teach dissolvable films comprising water-soluble film forming polymers such as pullulan (abstract). Column 4, line 66 through column 5, line 14 teach other film-forming agents such as hydroxypropylated starches. Leung et al. disclose in column 6, lines 21-54 and column 7, lines 8-47, examples of sweeteners and flavoring agents that can be used in the film. Leung et al. disclose in column 11, lines 45-61 a method of making a dissolvable film comprising mixing the film-forming ingredients and aqueous mixture to form a polymer gel, adding the oil mixture (substrate) to the gel and drying the mixture to form a film.

***Ascertainment of the difference between the prior art and the claims***  
**(MPEP §2141.02)**

Leung et al. do not teach the substance being encapsulated.

***Finding of prima facie obviousness***  
***Rational and Motivation* (MPEP §2142-2143)**

Applicant recites in claim 6 that that encapsulated substance is a volatile substance. A volatile substance is a substance that vaporizes or evaporates quickly. Since the claimed substance is volatile, it would have been obvious to one of ordinary skill in the art at the time the invention was made to encapsulate a volatile substance for the purpose of reducing the evaporation of the substance. Reducing the evaporation would allow the substance to be used at maximum strength for its intended purpose.

**(10) Response to Argument**

Applicant argues that the prior art reference of Leung et al. do not teach the claimed invention, especially adding the substance onto the film after the film is made. It is also argued that the substance of Leung et al. is not encapsulated. It is the position of the examiner that although the prior art does not teach encapsulating the substance or adding the substance to the film after the film is made, it would have been obvious. Encapsulating substances is well known throughout the pharmaceutical industry for various reasons, such as, delaying the release of a substance or protecting the substance from an unfavorable condition. This reasoning could lead one of ordinary skill in the art to making dissolvable films to coat the substance. One of ordinary skill would want to delay the release of the substance until it reaches the optimum conditions. Applying the substance onto the film would have been obvious for a few reasons. One reason is that adding the substance after mixing the film forming ingredients maintains the integrity of the substance. Another reason is that adding the substance after the film is made allows one of ordinary skill to ensure that the appropriate amount of substance is applied to the film to achieve the desired results.

Applicant also argues that Leung et al. makes no reference to the use of encapsulating substances particularly for the delivery of volatile substances. The examiner agrees, however, the encapsulation of volatile substances is well known in the art for the purposes of extending the shelf life and preventing the volatile substance from evaporating prematurely. Furthermore, by encapsulating the volatile substance,

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the efficacy of the substance will be maintained and not dissipate over time as a result of its volatile nature.

Furthermore, it is the position of the examiner that the difference between the instant invention and the prior art is a design choice. It is the position of the examiner that the invention is the method of making the film. Incorporating the volatile substance onto the surface of the film or within the film would have been obvious, since that the film will have the same property either way.

#### **(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618

Conferees:

Konata M. George